AUG 9 - 2005

OrthoScan HD

K051754

510 (k) Summary

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Part 807.92.

Date:	June 14, 2005
Name of Submitter:	OrthoScan, Inc. Suite 900 8585 E. Hartford Dr. Scottsdale, AZ 85255 480-503-8010
Corresponding Official:	Arlen Issette Chief Executive Officer
Device Proprietary Name:	OrthoScan, OrthoScan–HD
Classification Name:	System, X-ray, Fluoroscopic, Image-Intensified
Common/Usual Name:	OrthoScan Imaging System
Substantial equivalence:	The OrthoScan is substantially equivalent to the following systems which are currently marketed: 1. GE/OEC Medical Systems series 6800 mini view digital mobile imaging device. 2. Hologic/FluoroScan Imaging System Premier Encore mobile imaging device
Similarities/Differences:	Refer to the attached Specification Comparison, (Similarities/Differences). This chart compares the functional characteristics of the OrthoScan with these similar devices which are currently marketed.
Intended Use:	The OrthoScan mobile c-arm is designed to provide the physician with general fluoroscopic visualization of the patient including, but not limited to, surgical orthopedic procedures and critical and emergency care procedures.

User Characteristics:

The intended users of this product are doctors, surgeons, radiologists and technologists who will use this product in a hospital or clinical environment. It is anticipated that the majority of users will be orthopedic doctors, podiatrists and pediatricians, among others. It is anticipated that this product will be used on a daily basis by such users.

Users must be schooled in their medical fields and the use of x-ray equipment. They will be trained by OrthoScan specialists and/or qualified site personnel in the proper use of this product. The device labeling stipulates that only properly trained persons may operate this equipment.

General Description:

The OrthoScan is a mini C-arm mobile imaging system. The OrthoScan is used for processing and capturing live fluoroscopic images. Interfaces are provided for external peripheral devices such as controls, thermal printers, video cassette recorders and DICOM. The device is compatible with NTSC video outputs and 100 Base T Ethernet.

A number of algorithms are used in the image processing functions performed by the system. A detailed description of these algorithms is provided in the image processor functions specification attached hereto as Attachment A. The descriptions and formal definitions of these types of algorithms are well known. References on the subject would include:

Jain, Anil K., *Fundamentals if Digital Image Processing*, Prentice Hall, Inc. 1989. Castleman, Kenneth R., *Digital Image Processing*, Prentice Hall, Inc., 1979.

OrthoScan HD

The OrthoScan has the following physical characteristics:

- All components are contained in one mobile workstation
- An articulating arm is attached to the workstation and extends out from the main support to position the x-ray imaging components.
- All mechanical positioning of the workstation and articulating arm is manual (non-motorized).
- Power ratings are between 90VAC and 260 VAC and 3A to 6A. The system is powered by a detachable power cord.
- System power is isolated from input power by an isolation transformer.
- Internal x-ray generator produces voltages up to 80 kVp.
  Fluoroscopic operation:
  --- 40 to 80 kVp
  --- 20 to 100 uA (.020 to .100 mA)
  --- Automatic Exposure Rate Control

- Major components of the system include:
  --- Video monitor
  --- Input isolation transformer
  --- Circuitry for digital processing and x-ray control
  --- High voltage power supply
  --- X-ray tube
  --- Image Intensifier

Standards:

In addition to complying with the Federal Performance Standard for Diagnostic X-ray Imaging Systems (21 CFR Part 1020.30-32), the OrthoScan mobile C-arm is designed in accordance with guidelines established in the following standards:

NFPA 99, Standard for Health Care facilities
NFPA 70, National Electrical Code
UL 187, Standard for X-ray Equipment
CSA-C22.2 No. 601.1-M90, Medical Electrical Equipment
IEC 601-1, Medical Electrical Equipment, General Requirements for Safety
IEC 601-1-2, Medical Electrical Equipment, General Requirements for Safety, Electromagnetic Compatibility
IEC 601-1-3, Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray Equipment
IEC 601-2-7, Medical Electrical Equipment, Safety of HV/X-ay Generators
93/42/eec – Annex 1, Essential Requirements of the European Union Medical Device Directive

This concludes this 510 (k) Summary.

Attachment: OrthoScan Specification Comparison to Competitive Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 9 - 2005

Ms. Arlen Issette
American C-Arm, Inc., a.k.a.
OrthoScan, Inc.
8585 E. Hartford Drive, Suite 900
SCOTTSDALE AZ 85255

Re: K051754
Trade/Device Name: OrthoScan, OrthoScan HD
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobil x-ray system
Regulatory Class: II
Product Code: JAA and IZL
Dated: July 27, 2005
Received: July 27, 2005

Dear Ms. Issette:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051754 ~~Not Available~~

Device Name: OrthoScan, OrthoScan HD

Indications for Use:

The OrthoScan mobile c-arm is designed to provide the physician with general fluoroscopic visualization of the patient including but not limited to, surgical orthopedic procedures and critical and emergency care procedures.

The intended users of this product are doctors surgeons, radiologists and technologists who will use this product in a hospital or clinical environment. It is anticipated that the majority of user will be orthopedic doctors, podiatrists and pediatricians, among others.

Prescription Use ___X___ **(Part 21 CFR 801 Subpart D)** ~~**AND/OR**~~ **Over-The-Counter Use**_____ **(21 CFR 801 Subpart D)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Jessen

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051754